

REMARKS**Status of the Claims**

Claims 1-32 stand rejected. Claims 1-16 and 32 have been canceled without prejudice or disclaimer. Accordingly, claims 17-31 are pending and at issue.

Rejections Under § 35 U.S.C. § 102

Claims 1-6, 8-23, and 27-32 stand rejected as anticipated by U.S. Patent No. 6,485,703 issued to Cote et al. (Cote). Applicants respectfully disagree with the rejection of these claims, including claims 1-16 and 32. Although claims 1-16 and 32 have been canceled, applicants reserve the right to prosecute these claims in a continuation application.

Regarding claims 17-23 and 27-31, the Examiner states that Cote teaches the instantly claimed method steps. Claims 17-23, 27 and 30-31 recite gelling [a] mixture to form [a] *secondary* standard". Claim 28-29 recite calibrating [an] instrument with a *secondary* standard. As explained below, Cote does not disclose a standard of any kind, much less a secondary standard formed from gelling a mixture, or calibrating an instrument with a secondary standard. Therefore, Cote does not teach every element of the rejected claims.

The Examiner also takes the position that the intended use recited in claims 17-23 and 27-31 is not limiting because the product resulting from Cote's process can necessarily and inherently be used as a standard. Applicants respectfully disagree. The assay composition disclosed in Cote contains an analyte sensitive material (see, e.g., Cote, column 8, lines 7-27). The analyte sensitive material undergoes a change upon contact with the analyte. A product which changes upon contact with an analyte is not necessarily and inherently used as a standard.

Moreover, the product produced in Cote contains the analyte, and is thus not a secondary standard. As explained in the specification:

Standards which contain analyte "are inherently unstable and need to be prepared afresh for each calibration"

(see page 5, lines 17-19 of the present application). In contrast, a secondary standard simulates, but does not contain, the analyte of interest. A secondary standard "exhibits long term stability, so that it may be used repeatedly" (page 5, lines 15-23). A person of ordinary skill understands, by definition, that a product which contains appreciable amounts of the analyte cannot necessarily and inherently be used as a secondary standard.

As Cote does not disclose every element of the claimed process, does not produce a product that necessarily and inherently can be used as a standard, much less a secondary standard, applicants request that the anticipation rejection be withdrawn.

Rejections Under § 35 U.S.C. § 103

Claims 1-32 stand rejected as obvious over Cote in view of U.S. Pat. No. 6,077,669 issued to Little et al. (Little). According to the Examiner, the ordinary skilled artisan would recognize that the reading of the mixture without analyte must be determined to compare it with analyte containing material so that a meaningful value can be assigned to the analyte containing reading. The Examiner relies upon column 8 of Little for disclosing measuring an assay mixture without an analyte to assign a meaningful value to the assay which contains the analyte.

Contrary to the Examiner's suggestion otherwise, column 8 of Little does *not* disclose measuring an assay mixture without an analyte, and therefore does not disclose or suggest a process for preparing a secondary standard, or a process for calibrating an instrument with a secondary standard. Instead, known quantities of nucleic acid sequences, i.e., known quantities of analyte, are used as control or calibration samples. In particular, Little states:

For example, in one type of quantitation analysis, a plurality of known quantities of a nucleic acid sequence in respective **calibration samples (i.e., standards)** and an unknown quantity of

the nucleic acid sequence in a test sample are amplified in parallel during a time interval.

(Little, col. 6, lines 63-67) Little repeatedly refers "calibration samples" in the quantitative analysis techniques disclosed therein. (see Little, col. 7, lines 20-25, col. 7. lines 55-59, col. 8 lines 8-12). These "calibration samples (i.e. standards)" are not *secondary* standards, since they contain the analyte of interest.

Therefore, Little, like Cote, does not disclose or suggest secondary standards in general. Applicants respectfully submit that these references do not disclose or suggest a process for preparing a secondary standard, a process for preparing a secondary standard and request that the obviousness rejection be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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